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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,260	07/12/2000	KENGO AKIMOTO	001560-381	7267

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ART UNIT	PAPER NUMBER
1651	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/530,260	Applicant(s) Akimoto et al.	Examiner Irene Marx Art Unit 1651
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Oct 29, 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10, 13-16, and 23-26 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11, 12, and 17-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

The application should be reviewed for errors. Error occurs, for example in the spelling of “totalk” in claim 22.

Applicant's election with traverse of Group III, claims 11-12 and 17-22 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that because MPEP 1850 states “that an independent claim for a process specially adapted for the manufacture of said product ..” newly added claims 23-26 should be included in the same combination.

However this is not found persuasive because there is nothing in the method as claimed to suggest that this method of culturing various genera of fungi under unspecified conditions is specially adapted for the manufacture of a microbial lipid containing 72% by weight of arachidonic acid as claimed in the product claims. Note also that the term “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Here a special technical feature is lacking among the claimed inventions involving one or more special technical features because Kawashima *et al.* adequately demonstrates that a process of the cultivation of members of the recited genera having a defective desaturase at temperatures lower than the optimum growth is old and well known in the art (See, e.g., Example 2).

As to the arguments regarding claim 17 and claim 13 dependent thereon, the technical relationship between this claim and claim 13 is not clearly identified. As noted, the inventions do not match a permitted category as PCT Rule 13.2 does not provide for multiple products in one category. Two chemically distinct products are claimed in groups III and IV having distinct properties, i.e., a lipid containing arachidonic acid and a microorganism. An arachidonic containing lipid as claimed can be obtained by culturing a strain of wild type strain of a microorganisms followed by enrichment of arachidonic acid produced as adequately demonstrated by Shimada *et al.*, for example (See, e.g., Abstract).

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the

burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. .

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 101

Claims 11-12, and 17-22 are rejected under 35 U.S.C. 101 because the claims reads on the organism *per se* which is found in nature and thus, is unpatentable to applicant. It is suggested that applicant use the language "isolated" or "purified" in connection with the product to identify a product that is not found in nature. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Innoculant Co., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 21 appear to be substantial duplicates. Claims 12 and 22 appear to be substantial duplicates. Claim 21 is confusing in the recitation of "of arachidonic acid in fat". Antecedent basis for "fat" is unclear.

Claims 11-12, 17-22, are confusing in that it is not specified whether the weight percent is dry or wet weight. No new matter may be added.

Claims 17 and 18 are vague, indefinite, confusing and incomplete in depending on non-elected “any one of claims 13”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12 and 17-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Totani *et al.*.

The claims are drawn to a microbial lipid containing arachidonic acid at levels higher than 50% or 70%..

The cited reference discloses a microbial lipid containing arachidonic acid which appears to be identical to the presently claimed microbial lipid containing arachidonic acid enzyme. since the lipid from *Mortierella* contains 90% arachidonic acid (See, e.g., page 59, paragraph 2).

The referenced microbial lipid containing arachidonic acid appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the microbial lipid claimed, it shares substantially the same origin and contains substantially the same amount of arachidonic acid as claimed. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microbial lipid is not identical to the referenced microbial lipid with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microbial lipid is likely to inherently possess the same characteristics of the claimed microbial lipid particularly in view of the similar characteristics which they have been shown to share. Thus the claimed microbial lipid would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 11-12 and 17-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li *et al.*.

The claims are drawn to a microbial lipid containing arachidonic acid at levels higher than 50% or 70%..

The cited reference discloses a microbial lipid containing arachidonic acid which appears to be identical to the presently claimed microbial lipid containing arachidonic acid enzyme. since the lipid from *Mortierella* contains 72.5% arachidonic acid (See, e.g., page 138, first full paragraph and Table 6).

The referenced microbial lipid containing arachidonic acid appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the microbial lipid claimed, it shares substantially the same origin and contains substantially the same amount of arachidonic acid as claimed. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microbial lipid is not identical to the referenced microbial lipid with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microbial lipid is likely to inherently possess the same characteristics of the claimed microbial lipid particularly in view of the similar characteristics which they have been shown to share. Thus the claimed microbial lipid would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651